



FDA Real World Data Guidance for Device Research January 2, 2019

With FDA's focus on gathering "real-world" data on medical devices, the medical IRB will continue to receive registry and post-marketing surveillance studies. Such studies may include implantable devices, normally considered significant risk. The following excerpts from the FDA Guidance "[Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices](#)" provides direction on when a study would be exempt from Investigational Device Exemption (IDE) requirements vs. when a study would require an SR/NSR determination by the convened IRB. The examples may be useful as protocol descriptions may not clearly delineate **Interventional studies*** from **Observational studies****.

SR (IDE)/NSR (abbreviated IDE) determination by the convened IRB required:

- Data are being gathered to determine the safety and effectiveness of the device, and the process for gathering the data would influence treatment decisions, such administration would likely not be within the normal course of medical practice, and an IDE may be required.
- Prospective enrollment in a clinical investigation using the registry infrastructure to study a new, unapproved significant risk device would require an IDE.
- Similarly, a prospective, non-observational clinical investigation of a new indication for an approved device may require an IDE, depending on the risk determination.
- For example, a registry designed to determine the safety and effectiveness of an approved device for a new intended use would likely be subject to IDE requirements if physicians are instructed to treat specific patients or otherwise administer the device in a prescribed way for purposes of data generation, or when certain follow-up activities are performed for the purpose of research. If the plan to conduct such analyses impacts patient care, then the study may be subject to IDE requirements

Exempt from IDE requirements:

- Real-world surveillance where treatment decisions are not influenced by the expectation of conducting the future analysis
- No IDE is necessary for the general data collection activities of the registry, if it collects RWD on all uses of otherwise approved medical devices and it does not influence the treatment decisions and/or follow-up care that patients receive.
- Observational studies of a different use of a medical device, as long as the study does not impact how the device is administered, and the administration is within normal course of medical care. Treatment decisions must be made in the best interest of patients according to clinical judgement.

***Interventional Study** — "A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes".

****Observational Study** — "A study that does not involve any intervention (experimental or otherwise) on the part of the investigator; investigators observe without intervening other than to record, classify, count, and analyze results."